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5.0 510(k) SUMMARY

TRAUMASTAT™ Hemostatic Wound Dressing

MAY - 7 2008

Name and Address of Sponsor: **Ore-Medix, LLC**
3080 25th Street SE
Salem, OR 97302

Submitted by: **International Regulatory Consultants, L.C.**
7651 S. 700 West, Suite 105
Salt Lake City, UT 84047

Description of Device:

TRAUMASTAT™ Hemostatic Wound Dressing is a unique non-woven substrate comprised of porous polyethylene fibers highly filled with precipitated silica. This substrate is coated with chitosan, manufactured from ChitoClear™, a material consisting of the cellulosic polymer, poly-N-acetylglucosamine which is generally recognized as safe in accordance with 21 CFR 170.30. Each fiber of the wound dressing is approximately 20 to 100 micrometers in diameter. The wound dressing is provided in multiple lengths and widths to accommodate varying clinical situations as appropriate for its intended use. The dressing thickness is approximately 3 mm with an average density of approximately 0.15 gram/cc.

TRAUMATAT Hemostatic Wound Dressing is hermetically sealed in a poly foil pouch and electron beam sterilized.

Intended Use of Device:

Prescription Use: TRAUMASTAT Hemostatic Wound Dressing is intended for external temporary use to control moderate to severe bleeding.

Over the Counter Use (OTC): TRAUMASTAT Hemostatic Wound Dressing is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

Substantially Equivalent Predicate/Comparative Devices:

The TRAUMASTAT Hemostatic Wound Dressing is substantially equivalent to the following commercially available devices.

Product Name:	ChitoFlex™ Hemostatic Dressing
Manufacturer:	HemCon Inc.
510(k) Number:	K071519

Product Name:	QuikClot® eX™
Manufacturer:	Z-Medica Corporation
510(k) Number:	K072474

Safety and Effectiveness:

Based on in-vitro biocompatibility testing in accordance with FDA requirements and ISO 10993 for external communicating, breached surface blood contact devices for cytotoxicity, sensitization and skin irritation, the TRAUMASTAT Hemostatic Wound Dressing is concluded to be safe for its intended use. In-vivo animal testing conducted on swine models demonstrates the effectiveness of the hemostatic properties in arresting severely bleeding induced traumatic wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2008

Ore-Medix, LLC
% International Regulatory Consultants, LC
Mr. Donald F. Grabarz
Managing Director
7651 South 700 West, Suite 105
Midvale, Utah 84047

Re: K080648
Trade/Device Name: TRAUMASTAT™ Hemostatic Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 21, 2008
Received: April 22, 2008

Dear Mr. Grabarz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K080648

Device Name: TRAUMASTAT™ Hemostatic Wound Dressing

Indications For Use:

Prescription Use:

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Over the Counter Use:

TRAUMASTAT™ Hemostatic Wound Dressing is intended for external temporary use to stop bleeding of superficial wounds, minor cuts, and abrasions.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	X

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mcm

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K080648